

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,)
Plaintiff,)
v.) C. A. No. 06-222 (JJF)
IMPAX LABORATORIES, INC.,)
Defendant.)

**PLAINTIFF WYETH'S REPLY BRIEF IN SUPPORT OF ITS MOTION
TO STRIKE THE EXPERT REPORT OF IMPAX'S
PATENT LAW EXPERT, MARK E. NUSBAUM**

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INTRODUCTION

Impax does not contest that patent law experts are disfavored in this district and generally are not permitted to testify either about Patent Office practices and procedures or to provide legal opinions. Instead, Impax argues that Wyeth's motion to strike is "untimely" and should be deferred to a later stage of the case. Impax never explains, however, how Mr. Nusbaum's testimony would fare any better later in the case. Mr. Nusbaum's expert reports¹ should be stricken now so that Wyeth is not put to the additional burden and expense of having to further respond to plainly inadmissible testimony, having to depose Mr. Nusbaum, and having to defend the deposition of Wyeth's patent law expert.²

Impax's answering brief further highlights the impropriety of Mr. Nusbaum's expert reports. For example, Impax argues that Mr. Nusbaum's testimony would be helpful in explaining the materiality of Wyeth's alleged failure to disclose information to the patent examiner (D.I. 283 at 7). That testimony, however, is nothing more than a veiled attempt to have a lawyer provide legal argument on inequitable conduct from the witness stand. Mr. Nusbaum's testimony on this topic is unnecessary, unhelpful to the court, and should be stricken.

¹ Subsequent to the filing of Wyeth's motion, Impax filed a supplemental report for Mr. Nusbaum on October 23, 2007 that makes additional inequitable conduct allegations about the work resulting from a collaboration between Wyeth and Alza. (D.I. 284, Ex. 2).

² On October 31, 2007, Wyeth submitted a Rebuttal Expert Report by Mr. Richard Killworth, a patent law expert, responding to Mr. Nusbaum's report that was served on September 28, 2007. Mr. Killworth has not yet responded to the late-filed October 23, 2007 supplemental report of Mr. Nusbaum. Wyeth will withdraw any expert reports submitted by Mr. Killworth in the event the Court grants Wyeth's motion.

ARGUMENT

I. THERE IS NO REASON TO DELAY RULING ON THE MOTION TO STRIKE.

Impax devotes the bulk of its brief not to the merits of Wyeth's motion, but in arguing that the motion is "untimely." According to Impax, "[m]otions to strike or limit an expert's testimony are properly made close to the time of trial." (D.I. 283 at 1). Although such motions are sometimes heard at the pretrial conference or in connection with motions *in limine*, there is no principled basis not to decide the motion now.

In none of the cases that Impax cites did the Court rule that it could only preclude expert testimony in the context of motions *in limine* or the pretrial conference. Indeed, in *F. Hoffmann-LaRoche v. IGEN, Int'l, Inc.*, C.A. No. 98-318-JJF, Tr. 64 (D. Del. Oct. 24, 2000), this Court granted a similar motion to preclude a patent law expert from having access to confidential information under the protective order at an even earlier stage of the case.

There is no reason to delay ruling on this motion. Nothing in the later stages of this case will alter the admissibility of Mr. Nusbaum's proposed testimony. Moreover, the Pretrial Conference is scheduled for January 10, 2008, only two months from now. Impax does not even try to explain what will happen before the pretrial conference that would make Mr. Nusbaum's improper testimony proper or alter the outcome of this motion. Mr. Nusbaum's expert reports should be stricken so that Wyeth can avoid the needless burden and expense of further responding to clearly inadmissible testimony, as well as the expense of a round of unnecessary expert depositions.

II. MR. NUSBAUM'S PROPOSED TESTIMONY IS UNNECESSARY AND INADMISSIBLE.

A. This Court Generally Does Not Permit Patent Law Expert Testimony.

In its opening brief, Wyeth cited well-established law in this district that testimony from patent law experts regarding Patent Office practice and procedure generally is not permitted. *See, e.g.*, Judge Robinson's *Guidelines: Legal Expert Testimony in Patent Cases*. (D.I. 276 at 6-8). Impax argues that because this Court and courts in other jurisdictions have sometimes allowed expert testimony about Patent Office practice and procedure, the Court should do so here. (D.I. 283 at 5).

Impax ignores, however, that the Court in this case already has stated, *in response to Impax's inquiry*, that it would not permit testimony from a patent law expert absent extraordinary circumstances because the Court is the legal expert. (D.I. 87, Tr. at 15). Impax does not even attempt to meet this "extraordinary circumstances" standard. Impax likewise does not address this Court's comments in *F. Hoffmann-LaRoche v. IGEN Int'l Inc., supra*, that the Court "very consistent[ly]" excludes patent law experts in *both* bench and jury trials. Impax's argument that the Court made those comments in the context of a motion to preclude the expert from having access to confidential information rather than a motion to strike is a distinction without a difference. The Court's comments are no less pertinent because of the procedural context in which they arose.³ Impax also did not address Judge Sleet's recent ruling excluding

³ Impax's argument also is nonsensical. On the one hand, it argues that Wyeth's motion is untimely and premature. On the other it argues that Wyeth should have brought its motion long ago. In particular Impax argues that because Mr. Nusbaum was identified "under the protective order a long time ago, and Wyeth made no objections" to the disclosure of Wyeth confidential information to Mr. Nusbaum pursuant to that protective order, Wyeth is somehow estopped from objecting to Mr. Nusbaum's inadmissible testimony. (D. I. 283 at 2, n.8).

Mr. Nusbaum's similar proposed testimony on materiality in *Software AG v. BEA Sys., Inc.*, C.A. No. 03-739-GMS, Tr. 20 (D. Del. Apr. 4, 2005).⁴ This Court also recently precluded the testimony of another patent law expert who was proffered to walk through the prosecution histories of the patents-in-suit and describe the details of their prosecution. *See Alza Corp. v. Andrx Pharm., LLC*, C.A. No. 06-642 (JJF) (D. Del. Sept. 7, 2007) (Ex. A.)

Impax also argues that the Court's *Guidelines: Legal Expert Testimony in Patent Cases* are somehow inapplicable because they discuss jury trials, not bench trials. (D.I. 283 at 6). Impax does not explain, however, why patent law expert testimony would be more helpful in a bench trial, particularly given that the Court is the "legal expert." The cases that Impax cites where certain patent law expert testimony was admitted were, for the most part, jury trials.

B. There Are No "Extraordinary Circumstances" Justifying Mr. Nusbaum's Proposed Testimony

There are no "extraordinary circumstances" here that warrant testimony from a patent law expert. Although Impax tries to characterize Mr. Nusbaum's expert reports as describing Patent Office practice and procedure, they in fact are replete with opinions regarding what would have been important to a reasonable patent examiner and the supposed materiality of alleged misrepresentations. (See D.I. 276 at 3-6, & 10/23/2007 Suppl. Expert Report at ¶¶ 110-121, D.I. 284, Ex. 2). These are legal conclusions on substantive patent law that are routinely excluded by this Court. *Revlon Consumer Prod. Corp. v. L'Oreal S.A.*, 1997 U.S. Dist. LEXIS

⁴ Mr. Nusbaum's expert testimony also was excluded in at least two other cases. In *Applied Materials Inc. v. Advanced Semiconductor Materials Am. Inc.*, No. C 92-20643, 1995 WL 261407, at *2-4 (N.D. Cal. Apr. 25, 1995), the Court held that Mr. Nusbaum should not be permitted to testify about the effect and materiality of the prior art because he "is not a technical expert" or "skilled in the relevant art." (*Id.*). In *Roche Diagnostics Corp. v. Apex Biotechnology Corp.*, 1:04-cv-0358-LJM-VSS, Order (S.D. Ind. May 16, 2005), the Court granted defendants' joint motion *in limine* to exclude the testimony of Roche's patent law expert, Mark E. Nusbaum. (Ex. B).

4117, *7-8 (D. Del. Mar. 26, 1997). Impax also does not explain why Mr. Nusbaum's testimony on materiality and duty of disclosure would be helpful to the Court.⁵

Although Impax acknowledges that "the Court is undoubtedly familiar with certain aspects of PTO practice and procedure already," it argues that "Mr. Nusbaum's testimony could quickly pinpoint those particular sections of the applications...that are important to Impax's case." (D.I. 283 at 6). It also argues that "Mr. Nusbaum could point out which sections of the Manual of Patent and Examining Procedure (MPEP) Impax relies on." (D.I. 283 at 7). Wyeth respectfully submits that pointing out the important parts of Impax's case to the Court is the role of Impax's attorneys, not Mr. Nusbaum.

Next, Mr. Nusbaum attempts to cast doubt on the presumptive validity of an issued patent by stating that, for example, "patent examiners operate under time constraints" (Suppl. Expert Report at ¶ 21, D.I. 284, Ex. 2), and "[t]here are a number of patent validity-related issues that cannot be analyzed by a patent examiner due to a lack of information relating to such issues" (*id.* at ¶ 24). Although Impax tries to characterize this as testimony regarding Patent Office practice and procedure, it is an impermissible opinion on validity. *See 3M v. Appleton Papers, Inc.*, 1998 U.S. Dist. LEXIS 22597 at *5 (D. Minn. Jun. 24, 1998) ("The Court finds that Henon's proposed testimony concerning the limitations placed upon patent examiners and the alleged deficiencies of the examination in this case conflict with the statutory presumption of validity. The Court will not permit Appleton to challenge the patent with evidence that undermines the statutory presumption.").

⁵ Impax also argues that Mr. Nusbaum is entitled to rely on the opinions of other experts in his testimony. (D.I. 283 at 7). Although Wyeth does not dispute this, the fact remains that Mr. Nusbaum has no non-cumulative testimony to offer on the substantive issues in this case that could be helpful to the Court.

Last, Impax argues that Mr. Nusbaum's supplemental report supplies needed explanatory testimony of the reexamination proceedings of the Alza patent, U.S. Patent No. 6,440,457. (D.I. 283 at 6). His supplemental report, however, makes ***no*** reference whatsoever to the Alza reexamination proceedings. (*See* D.I. 284, Ex. 2 at ¶¶ 110-121). Mr. Nusbaum's testimony cannot be helpful on a topic that it does not discuss or reference. In any event, the Court does not need a lawyer to explain the reexamination from the witness stand any more than it needs a lawyer to do so with respect to the prosecution history.

CONCLUSION

For the reasons set forth in Wyeth's opening brief and herein, Mr. Nusbaum's patent law expert report and supplemental expert report should be stricken.

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November 2, 2007
1305398

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on November 2, 2007, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

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I also certify that copies were caused to be served on November 2, 2007 upon the following in the manner indicated:

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ALZA CORPORATION and :
McNEIL, PPC, INC. :
: Plaintiffs, :
v. : : Civil Action No. 05-642-JJF
: ANDRX PHARMACEUTICALS, LLC and :
ANDRX CORPORATION :
: Defendants. :

ORDER

WHEREAS the Court held a Pretrial Conference on September 6, 2007;

WHEREAS, the Court discussed with counsel the setting of a date for trial, as well as other issues related to the pending trial, including Plaintiffs' Motion to Preclude Testimony of Bruce H. Stoner, Jr., Esq. (D.I. 123);

WHEREAS, the Court has concluded, based on these discussions, the following procedures will allow for an efficient and fair presentation of each party's case at trial;

NOW THEREFORE IT IS HEREBY ORDERED that:

1. A Bench Trial in this matter will commence on **Monday, December 10, 2007, at 9:30 a.m.** Each side will be allocated a total of fifteen (15) hours in court trial time to present their case.
2. The parties will submit to the Court pretrial briefing regarding the findings of fact and conclusions of law as described at the Pretrial Conference. The briefing

shall be completed by December 3, 2007.

3. Plaintiffs Motion to Preclude Testimony of Bruce H. Stoner, Jr., Esq., (D.I. 123) is GRANTED.

September 7, 2007

DATE


JOSEPH J. FARA, JR.
UNITED STATES DISTRICT JUDGE

EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ROCHE DIAGNOSTICS CORPORATION,)	
<i>et al.</i> ,)	
Plaintiffs/Counterclaim Defendants,)	
)	
vs.)	
)	1:04-cv-0358-LJM-VSS
APEX BIOTECHNOLOGY CORP., <i>et al.</i> ,)	
Defendants/Counterclaim Plaintiffs.)	
)	
ROCHE DIAGNOSTICS CORPORATION,)	
<i>et al.</i> ,)	
Plaintiffs/Counterclaim Defendants,)	
)	
vs.)	1:04-cv-1187-LJM-VSS
)	
HOME DIAGNOSTICS CORPORATION, INC.,)	
Defendant/Counterclaim Plaintiff.)	
)	

ENTRY FOR MONDAY, MAY 16, 2005

THE HONORABLE LARRY J. McKINNEY, CHIEF JUDGE

Parties appear by counsel for final pretrial conference during which the Court heard argument on plaintiffs'/counterdefendants, Roche Diagnostics Corporation, Roche Diagnostics Operations, Inc., and Corange International, Ltd. (collectively, "Plaintiffs"), Motion *in Limine* to Exclude the Testimony of Mark E. Nusbaum, defendants'/counterclaimants', Apex Biotechnology Corp., Hypogurad USA, Inc., Medline Industries, Inc., and Home Diagnostics Corporation, Inc. (collectively, "Defendants"), expert. The Court **GRANTED** the motion *in limine*.

The parties also discussed with the Court certain discovery issues that may effect the ability of Defendants to put on their inequitable conduct defense case. The Court advised the parties to do the best they can to complete the necessary discovery prior to the trial and to bring any deficiencies to the Court's attention during trial if necessary.

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